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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,584 | 02/01/2001 | Andreas Bosio | P66095US0 | 7032 |

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WASHINGTON, DC 20004

EXAMINER

HORLICK, KENNETH R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1637

19

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,584

Applicant(s)

BOSIO ET AL.

Examiner

Kenneth R Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. This application is now being examined by a different examiner, as set forth at the end of this Office action.

2. Claims 11-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 11-22 and 25 are confusing because of the language “characterized in that”, as the scope cannot be determined. It is suggested that conventional U.S. patent claim terminology be used in amended claims, such as “comprising”, “consisting of”, or “wherein”.

B) Claim 11 is further confusing because of “sand” in line 5.

C) Claims 11-22 and 25 are confusing because of the language “linked...through bifunctional spacers and bifunctional linkers”, as the nature of the link with oligo- or polynucleotides cannot be determined. That is, this might or might not encompass spacer-polynucleotide species, linker-polynucleotide species, spacer-linker-polynucleotide species, or any combination thereof. Thus, if the spacer-linker-polynucleotide embodiment as shown in Fig. 1 is contemplated, it is suggested that this be made clear in amended claims.

D) Claims 11-22 and 25 are confusing because “oligo- or polynucleotide” (singular) in claim 11, 12, and 25 lacks proper antecedent basis – this is referred to previously in claim 11 in the plural form. Correction is required.

E) Claims 11-22 and 25 are further confusing because of “e-” in the 4th-to-last line of claim 11; it would appear that “3-” is intended.

F) Claims 11-22 and 25 are further confusing because of improper Markush language in claims 11, 16, and 17; correction is required.

G) Claim 13 is further confusing because of the relative language “mainly consisting of”.

H) Claim 14 is confusing because of the language “such as”.

I) Claims 22-25 are confusing because they are drawn to methods, but no active steps are recited. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). It is noted that claims 22, 23, and 25 also lack the typical “comprising” or “consisting of” language present in method claims.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al., in view of Ishii et al. (US 5,474,895), and further in view of Sobol et al. (US 5,543,296).

These claims relate to supports, methods of use, and methods of making, wherein the supports comprise oligo- or polynucleotides linked to the support via a certain spacer and a certain linker, and said polynucleotides have a length of from 200 to 600 bp, and said polynucleotides are bound to the linker through a primary amino group attached to the end of the polynucleotides, and said polynucleotides are prepared by amplification.

Guo et al. teach supports with bound oligonucleotides, wherein the oligonucleotides are bound to the support via a linker which comprises both the spacer and linker moieties as claimed (see especially Fig. 1).

Guo et al. do not teach bound oligonucleotides of 200-600 bp length, nor binding of the oligonucleotides to the linker via a primary amino group, nor preparation of the oligonucleotides via amplification.

Ishii et al. disclose attachment of oligonucleotides to functional groups on solid supports via an amine group at the terminus of an alkyl linker, said linker appended to either end of the oligonucleotide (see column 9, line 53 to column 10, line 13).

Sobol et al. disclose hybridization assays wherein amplified nucleic acid target sequences are bound to a solid support (see column 14, lines 38-45). In Tables 1-5, it can be seen that several of the amplified nucleic acids of Sobol et al. are between 200-600 bases in length. It is also noted that amplification products within this size range were indisputably well known and conventional in the art at the time of the invention.

One of ordinary skill in the art would have been motivated to substitute the poly-T-linked oligonucleotide of Guo et al. with an oligonucleotide having an alkylamine linker because Ishii et al. disclosed that such alkylamine-modified oligonucleotides were a convenient means of attaching oligonucleotides to functional groups on solid supports. The skilled artisan would have been further motivated to use amplification products of between 200-600 bp in length in the method of Guo et al. because Sobol et al. disclosed that it was desirable to immobilize amplification products in this size range to solid supports for hybridization assays. Thus, it would have been prima facie obvious to

one of ordinary skill in the art at the time of the invention to make and use the claimed supports.

4. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al., in view of Schena et al. (1996).

This rejection was made in the previous Office action mailed 10/02/02 over claim 9, which is essentially the same as pending claims 23 and 24. As this rejection was not traversed in the response filed 03/03/03, it is MAINTAINED. It is also pointed out that independent claim 23 does not have any limitations relating to the particular support of claim 11.

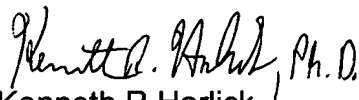
5. No claims are free of the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

May 21, 2003